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| APPLICATION NO.            | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|----------------------------|-------------|----------------------|---------------------|------------------|
| 09/787,397                 | 05/17/2001  | Masaaki Goto         | FJIN-107            | 2388             |
| 23290                      | 7590        | 05/26/2004           | EXAMINER            |                  |
| HOLLANDER LAW FIRM, P.L.C. |             |                      | SAOUD, CHRISTINE J  |                  |
| SUITE 305                  |             |                      | ART UNIT            |                  |
| 10300 EATON PLACE          |             |                      | PAPER NUMBER        |                  |
| FAIRFAX, VA 22030          |             |                      | 1647                |                  |

DATE MAILED: 05/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                                       |                                    |  |
|------------------------------|---------------------------------------|------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>09/787,397  | <b>Applicant(s)</b><br>GOTO ET AL. |  |
|                              | <b>Examiner</b><br>Christine J. Saoud | <b>Art Unit</b><br>1647            |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 03 March 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 13-29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 13-29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>030304</u> . | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Claim 13 has been amended, claims 1-12 have been canceled and claims 21-29 have been added in the amendment of 03 March 2004. Claims 13-29 are pending and under examination in the instant Office action.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Any objection or rejection of record which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

Applicant's arguments filed 03 March 2004 have been fully considered but they are not deemed to be persuasive.

### ***Election/Restrictions***

Applicant's continued argument regarding the holding of Lack of Unity is noted, but moot in light of the cancellation of the claims in question.

### ***Claim Rejections - 35 USC § 112***

Claims 13-29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention for the reasons of record as applied to claims 13-20.

Applicant asserts that *in vivo* data is not necessary in order to satisfy the enablement requirement. The Examiner does not disagree and it was never asserted in

the previous Office action that *in vivo* data was required. Applicant argues at page 10 of the response that the Examiner "has not provide any reason or evidence as to why the specific model given in the specification does not correlate to the treatment of obesity". Applicant's argument is not persuasive because the previous Office action was replete with explanation and reasoning. With regard to correlation of *in vitro* inhibition of 3T3/L1 cells to prevention of obesity, one of ordinary skill in the art would not find activity in this assay as predictive for prevention of obesity because obesity is a condition that is not only physiological (disease related, genetically related, etc.) but is also a psychological condition. A person who is depressed may eat more and thereby, gain weight to the point of being obese. One of ordinary skill in the art would not conclude that the administration of a compound which exhibits adipogenesis inhibitory activity in cell culture would be effective for prevention of obesity. At present, there is no therapeutic method or composition which has been shown to be effective for prevention of obesity. Because the state of the art is such that there is no art recognized pharmaceutical for the prevention of obesity, one of ordinary skill in the art would not reasonably conclude that a compound which exhibits adipogenesis inhibitory activity in cell, without more information, would be effective for prevention of obesity because no such compound is currently known to exist. Even extreme surgical methods, such as stomach bi-pass surgery, are not completely effective in prevention or treatment of obesity in an individual who is determined to overeat. Therefore, the claims are not enabled for prevention of obesity by the administration of stanniocalcin, absent evidence to the contrary.

With regard to a method of treating obesity by the administration of stanniocalcin, reasons were given in the previous Office action as to why the *in vitro* assay was not predictive (i.e. did not correlate) with the desired *in vivo* activity. Applicant cites Lea-Currie et al. as evidence that the *in vitro* assay correlates with *in vivo* activity (see page 10-11 of response). However, this does not appear to be fair reading of Lea-Currie et al. The reference indicates that its purpose was to determine whether known *in vivo* effects were due to a particular *in vitro* cellular activity (3T3-L1 cells). Therefore, the compound being administered was already known to have antiobesity actions and Lea-Currie et al. was investigating a possible mechanism of action via 3T3-L1 cells. However, it is also noted that additional mechanisms of action are discussed, indicating that this one activity is not necessarily the only activity of the compound which results in its antiobesity activity. In the process of investigating biological activities of compounds, *in vitro* assays are used to establish possible biological effects. However, not all activities demonstrated *in vitro* result in an *in vivo* use for the compound. This can be due to the lack of correlation of the *in vitro* assay with an *in vivo* condition, due to the complexity of the condition to be treated (i.e. multiple levels of control of the condition), or even possibly due to a different biological effect when the compound is administered *in vivo*. Applicant has not established that biological activity in the 3T3-L1 assay is predictive of a biological effect of treating obesity. The previous Office action indicated that one of ordinary skill in the art at the time the instant invention was made would not consider the 3T3-L1 assay predictive of treatment of obesity because weight control is a multi-factorial process in which the body regulates energy balance. The body

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processes a number of different signals in process of maintaining energy balance. Inputs come from the brain, temperature, exertion, blood glucose levels, the GI tract, etc. The body's control center then decides if food is to be ingested. The biological activity of stanniocalcin on adipocytes is but one factor in this very complicated, multi-factorial system in which the body is attempting to maintain its energy balance, which includes maintaining a reserve of energy. This is one of the reasons why weight loss is so difficult and why obesity is such an enormous health issue in the country today. The instant specification provides no evidence that the administration of stanniocalcin is effective for treatment of obesity. One ordinary skill in the art would not find the claimed method enabled because the experimental model which is exemplified in the specification is not predictive of an effective treatment of obesity. Therefore, the invention as a whole is not enabled.

The specification demonstrates that stanniocalcin exhibits adipogenesis inhibitory effect in adipocytes. Method claims directed to this biological activity, which do not recite treatment of obesity, are enabled by the specification as originally filed. An art search in this area has been conducted and claims directed to a method of inhibiting adipogenesis by the administration of stanniocalcin would be free of the prior art and enabled by the specification. However, claims to methods of treatment and methods of prevention of obesity are not allowable for the reasons of record and for those reasons given above.

### ***Conclusion***

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action (over the newly submitted claims). Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine J. Saoud whose telephone number is 571-272-0891. The examiner can normally be reached on mttr, 8:00-2:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

**CHRISTINE J. SAOUD  
PRIMARY EXAMINER**

*Christine J. Saoud*